



STATE OF TENNESSEE
DEPARTMENT OF HEALTH
DIVISION OF HEALTH LICENSURE AND REGULATION
OFFICE OF HEALTH RELATED BOARDS
BOARD OF PHARMACY
665 MAINSTREAM DRIVE
NASHVILLE, TENNESSEE 37243
PHONE: (615) 741-2718 FAX: (615) 741-2722
<http://tn.gov/health/topic/pharmacy-board>

INSTRUCTIONS FOR MANUFACTURER LICENSE

Pursuant to Rule 1140-09-.01(1): Every manufacturer, outsourcing facility, oxygen supplier or wholesaler/distributor, before engaging in the manufacture, sale or distribution of prescription drugs and prescription devices in this state, must be licensed by the Board in accordance with this chapter. (2): An applicant with physical facilities in this state must obtain and display prominently a separate license for each principal place of business where the applicant manufactures or distributes prescription drugs and prescription devices.

Pursuant to Rule 1140-09-.02 (2): Applicants seeking to register as manufacturers or outsourcing facilities shall provide the following materials to the Board of Pharmacy: (a) Proof of registration with the Food and Drug Administration as a manufacturer or outsourcing facility and the most current inspection by that agency, or correspondence or other written proof from the Food and Drug Administration which states that registration with that agency is unnecessary

Pursuant to Public Chapter 430, signed into law by Governor Haslam on May 16, 2013, all Tennessee-licensed manufacturers, wholesalers and distributors of controlled substances, including tramadol, must regularly submit a report in Automation of Reports and Consolidated Order System *(ARCOS) format the Board of Pharmacy of all CII-CV controlled substance distributions to a Tennessee licensee.

*For instructions regarding data submission for Tennessee-Licensed Manufacturers and Wholesalers/Distributors, please visit: <https://apps.health.tn.gov/apps/ARCOS/index.shtml>.

NOTE: A new application must be submitted to the Tennessee Board of Pharmacy, along with the required application fee(s), anytime there is a Name, Location, or Ownership change.

ALL APPLICANTS

All documentation required to be submitted by you must be mailed directly to:

Tennessee Board of Pharmacy
665 Mainstream Drive
Nashville, TN 37243
(zip code 37228 for courier service only)

All application fees are Non-Refundable. Attach a check or money order made payable to the Tennessee Board of Pharmacy. **NOTE:** Please see the rules below to determine if the facility is required to also register for controlled substances and/or sterile compounding.

| | |
|---------------------------------|----------|
| Registration Fee (required) | \$525.00 |
| State Regulatory Fee (required) | \$10.00 |
| *Controlled Substance Fee | \$40.00 |
| **Sterile Compounding Fee | \$250.00 |

***Pursuant to Rule 1140-01-.11:** No licensee may obtain, possess, administer, dispense, distribute, or manufacture any controlled substance in this state, and no representative of a manufacturer or wholesaler/distributor may distribute any controlled substance in this state, without obtaining a controlled substance registration from the board.

****Pursuant to Rule 1140-01-.12 (1):** No licensee may compound, manufacture, prepare, propagate, or process any sterile product to be dispensed, sold, traded, or otherwise distributed in or from this state without first obtaining a sterile compounding modifier registration from the Board of Pharmacy.

- Submit a list of owners, partners, board of directors or corporate officer.
- Criminal background check is required for the owner or manager of the facility seeking licensure. You may register at <http://tn.gov/health/article/CBC-instructions>.
- Copy of registration and current inspection report issued by the Food and Drug Administration (FDA) or a written statement from the FDA stating that registration with the agency is unnecessary
- Complete the attached survey

NOTE: If you are a virtual manufacturer and utilizes a Third Party Logistic Provider (3PL) for manufacture, sale or distribution of its product(s), the application must be completed to reflect the 3PL business name and address under the section for “Facility Address”. The business name and address on all supporting documents must correspond with the information provided on the application.

Please allow ten (10) business days for information mailed to the board’s office to be received. Special courier services will not appreciably reduce the time it takes to process an application. It takes approximately eight (8) weeks for a license to be issued.

Upon receipt of the application, an administrative member of the Board of Pharmacy will conduct a preliminary review of the application. If additional information is required, notification will be provided via regular mail or electronic mail.

Application for resident facility will be forwarded to a Board of Pharmacy investigator for an inspection. Upon receipt of a satisfactory inspection report, the application will undergo a final review and a licensee will be issued.

Upon receipt of all required documents, applications for non-resident facility will undergo a final review and a license will be issued.

Once an application has been approved, please allow 7-14 business days for receipt of the license certificate.

Please limit phone calls and/or emails to the board office regarding the status of an application. You may verify the license status here: <https://apps.health.tn.gov/facilityListings/>

OUT OF STATE APPLICANTS

In addition to the items required for all applicants, out of state applicants must also provide the following:

- Copy of the license issued by the state which the facility is located
- Copy of the inspection report completed within the last 12 months or a statement from the resident state licensing agency explaining its inspection policy (**IF NOT REGISTERED WITH THE FDA**)
- Copy of the DEA certificate



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APPLICATION FOR MANUFACTURER LICENSE

APPLICATION FOR:

- ☐ New License
☐ Name Change

TN License Number (if applicable): _____

- ☐ Location Change
☐ Ownership Change

CORPORATE MAILING ADDRESS:

| | | |
|--------------------------|-------|---------------------|
| Company Name | | |
| Address Line 1 | | |
| Address Line 2 | | |
| City | State | Zip Code |
| Corporate Contact Person | | Corporate Telephone |

FACILITY ADDRESS:

| | | |
|---------------------------|-------|------------------|
| Company Name | | |
| Name of 3PL if applicable | | |
| Address Line | | |
| City | State | Zip Code |
| Manager at Facility | | Telephone Number |

Please complete if applying for a Name, Location, or Ownership change:

| | | |
|-------------------------|-------|----------|
| Previous Company Name | | |
| Previous Address Line 1 | | |
| Previous Address Line 2 | | |
| City | State | Zip Code |

Do you wish to receive notifications, including renewal notification, from Department of Health via email? Please note, by opting in, all correspondence from the Department of Health will be delivered to the email address on file for you. You will no longer receive physical mail from our office. ____ Yes ____ No

CONTROLLED SUBSTANCES: Yes ☐ No ☐ **DEA Number:** _____

STERILE COMPOUNDING: Yes ☐ No ☐ If no, you are required to immediately report to the board any changes in the manufacturer/wholesaler/distributor business model.

SELL/DISTRIBUTE DRUGS OR DEVICES TO: ☐ Wholesalers ☐ Distributors ☐ Community Pharmacies
☐ Hospital Pharmacies ☐ Long-Term Care Facilities ☐ Veterinarians ☐ Researchers ☐ Prescribing Practitioners
☐ Other: _____

Is this wholesaler/distributor a repackager? Yes ☐ No ☐

If the Manufacturer, Wholesaler/Distributor or Outsourcer has an NPI number, please provide: _____

CORPORATIONS: Must attach a list of your Board of Directors with the address of the corporation. If not a corporation, please provide a list of owner(s), partner(s), or officer(s), including addresses and phone numbers.

TYPE OF OWNERSHIP:

- ☐ Sole Proprietorship
- ☐ Partnership
- ☐ Corporation
- ☐ LLC
- ☐ Other: _____

This application is completed by: (Check one) ☐ **OWNER** ☐ **OFFICER OF CORP.** ☐ **ADMINISTRATOR**

Does the Owner, Officer of Corporation or Administrator have any charges involving moral turpitude or violation of pharmacy law, or any other laws pending against the them? ☐ **Yes** ☐ **No** (If yes, please explain such charges or violations in detail; even to reporting minor infractions of pharmacy laws, liquor or narcotic laws regulations, including dates.)

Does the facility possess a printed or electronic version of the TN Law Book? ☐ **Yes** ☐ **No**

Note: Every business licensed by the Tennessee Board of Pharmacy must possess a copy of the board publication which contains Pharmacy Law and Regulations; the Tennessee Drug Control Act; and the Tennessee Food, Drug & Cosmetic Act (applicable parts only).

Attach a list of the owners, officers or directors to this application.

AFFIDAVIT AND RELEASE

I, _____, of _____
(Applicant's Name) (City) (State)

affirm that I am the owner for this manufacturer listed in this application.

I affirm that I am the owner and accountable to the Board of Pharmacy for this practice site's compliance with all state statutes and regulations governing the practice of being a licensed manufacturer in Tennessee.

I affirm that before engaging in the manufacture, sale or distribution of prescription drugs and prescription devices in this state, that this practice site must be licensed by the Tennessee Board of Pharmacy

THIS CERTIFIES THAT THE INFORMATION SUBMITTED BY ME IN THIS APPLICATION IS TRUE AND COMPLETE TO THE BEST OF MY KNOWLEDGE AND BELIEF.

SIGNATURE

DATE



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**TENNESSEE BOARD OF PHARMACY
MANUFACTURER COMPLIANCE SURVEY**

To ensure regulatory compliance and promote product safety, the Tennessee Board of Pharmacy is surveying all entities seeking licensure in Tennessee as a Manufacturer. Please answer the questions below and return to the Board office. You may respond by mail to Tennessee Board of Pharmacy 665 Mainstream Drive, Nashville, TN 37243; by fax to 615-741-2722; or by scanning and e-mailing to: PharmacyHealth@tn.gov

Pursuant to Tennessee Code Annotated (T.C.A.) §63-10-305 (8), the request to complete and return this survey is considered a lawful order of the Board of Pharmacy. Response is required before a license will be issued. Please retain a copy of your response at the firm's location.

NAME OF FACILITY: _____

ADDRESS OF FACILITY: _____

CITY, STATE, ZIP: _____

PHONE NUMBER: _____

NAME OF PERSON RESPONSIBLE FOR RESPONDING: _____

MANUFACTURER:

T.C.A. §63-10-204 (21) *“Manufacturer” means any person, except a pharmacist compounding in the normal course of professional practice, engaged in the commercial production, preparation, propagation, conversion or processing of a drug, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical synthesis, or both, and includes any packaging or repackaging of a drug or the labeling or relabeling of its container and the promotion and marketing of such drugs or devices;*

1. By this definition, is this firm a “manufacturer”? ☐ Yes ☐ No

If “no”, please provide a description of the business and the reason you do not feel it meets this definition: _____

If “yes”, please answer the following questions:

Are you a virtual manufacturer? ☐ Yes ☐ No

2. Is the firm licensed or registered with FDA? ☐ Yes ☐ No

If “no”, please provide a brief explanation why: _____

If “yes”, please attach proof of the FDA license or registration to your response to this survey.

3. How many different products has the firm manufactured in the past 12 months? _____

Please attach a list of all products manufactured at the facility in the past 12 months along with the volume produced of each item.

4. Are any sterile products manufactured? ☐ Yes ☐ No

If “yes”, please attach a list of all sterile products manufactured and the volume produced of each item.

5. Does the firm ship product into other states? ☐ Yes ☐ No

If “yes”, please attach a list of all other states into which shipment occurs.

6. Is the firm licensed in all states listed in Question 5? ☐ Yes ☐ No

If “yes”, please attach proof of licensure.

If “no”, please describe why not: _____
